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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,854	07/17/2003	Chiang J. Li	25627-501	2920

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EXAMINER

LEWIS, AMY A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,854

Applicant(s)

LI, CHIANG J.

Examiner

Amy A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/17/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 56, 59, 62, 65, 68, and 71, drawn to a cell cycle checkpoint activation modulator, classified in class 514, subclasses 454 or 437.
- II. Claims 1-54, drawn to a method of treating cancer comprising administering a modulator of cell cycle checkpoint activation to a subject in need thereof, classified in class 514, subclasses 454 or 437.
- III. Claims 57, 60, and 63, drawn to a method of treating cancer comprising administering a modulator of cell cycle checkpoint activation, identified by a method of screening for a cell checkpoint activation modulator, to a subject in need thereof, classified in class 514, subclasses 454 or 437.
- IV. Claims 66, 69, and 72, drawn to a method of treating cancer comprising administering a modulator of cell cycle checkpoint activation, identified by a method of screening for a compound effective for treating cancer, to a subject in need thereof, classified in class 514, subclasses 454 or 437.
- V. Claims 55, 58, and 61, drawn to a method of screening for a cell checkpoint activation modulator, classified in class 435, subclass 7.21.
- VI. Claims 64, 67, and 70, drawn to a method of screening for a compound effective for treating cancer, classified in class 435, subclass 7.23.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I & II, I & III, and I & IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, which is a method of treatment.

Inventions I & V and I & VI are related as product and process of finding the product, i.e., a method of use of a product to find properties of the compound/composition. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used in a materially different process of using that product; the product can be used in a method of treating cancer. Additionally, the method of inventions V and VI are directed to an assay, which could identify compounds other than those of Invention I.

Inventions II & III and II & IV are related as combination and subcombination. (Invention III is a combination of Inventions II and V, and Invention IV is a combination of Inventions II and VI). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for

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patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the method of treatment (of Invention II) does not require that the compound administered be identified through a screening method for cell checkpoint activation modulation activity (of Invention III) or identified through a screening method for effectiveness against cancer (of Invention IV); the compound may be administered in a method of treatment without the step of screening.

The methods of Inventions II & V and II & VI are directed to patentably distinct inventions. These methods are distinct since the practice of the invention of Invention II does not require the particulars of the screening method of Invention V or VI, nor does the screening method of Invention V or VI require the practice *per se* of the method of treatment of Invention II. For example, one would not need to screen for a compound that is a cell checkpoint activation modulator (of Invention V) in order to administer cell cycle checkpoint activation modulator therapy. Nor would one necessarily need to administer cell cycle checkpoint activation modulator therapy after screening for the compound; one could just identify a compound. In the same manner, one would not need to screen for a compound effective for treating cancer (of Invention VI) in order to administer anti-cancer therapy.

Inventions V & III, V & IV, VI & III, and VI & IV are related as combination and subcombination. (Invention III is a combination of Inventions II and V, and Invention IV is a combination of Inventions II and VI). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination

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as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the method of screening (of Inventions V and VI) do not require that the compound be administered as part of a method of treatment; the compound could simply be screened and never administered.

Inventions V & VI are patentably distinct and/or independent. Invention V is drawn to a method of screening for a cell checkpoint activation modulator and Invention VI is drawn to a method for screening for a compound effective for treating cancer. They have different functions and different modes of operation. For example, one could discern if a compound was effective for treating cancer (by administering it to tumor cells as in Applicant's Experiment described on Table 1 p. 33 of the specification and observing the rate of cell death), without determining if the compound was modulating cell checkpoint activation. Nor would one necessarily determine that a compound was effective against cancer if it is a modulator of cell checkpoint activation. One is not needed for the practice of the other and the search of Invention V would not have resulted in a complete search of the patent and non-patent technical literature for Invention VI.

Inventions III & IV are patentably distinct and/or independent. The methods of treatment of Inventions III and IV are distinct since the practice of Invention III does not require the particulars of Invention IV. In a method of treating cancer including a method of screening for the compound administered, one would not necessarily need to determine if the compound was modulating cell checkpoint activation in order to determine if the compound was effective for

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treating cancer. One is not needed for the practice of the other and the search of Invention III would not have resulted in a complete search of the patent and non-patent technical literature for Invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Applicant is required under 35 U.S.C. 121 to elect one of Inventions I-VI and in addition, a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

A. Applicant should elect one specific cell cycle checkpoint activation modulator compound, such as 3,4-dihydro-2,2-dimethyl-3-(3-methyl-2-butenyl)-2H-paphthol[1,2-b]pyran-5,6-dione from the Markush group of claim 9, for the practice of each one of the inventions above.

B. Applicant should also elect one transcription factor from the group consisting of E2F-1, E2F-2, or E2F-3.

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Applicant should elect one specific cell cycle checkpoint activation modulator compound (item A) and one specific transcription factor (item B) for the practice of the inventions as defined in I-VI.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. **An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.**

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the species to be examined, even though the requirement be traversed (37 CFR 1.143).

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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